UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,658	11/29/2001	James M. Coull	BP0002-US	5256

23544 7590 10/28/2005

APPLIED BIOSYSTEMS
500 OLD CONNECTICUT PATH
FRAMINGHAM, MA 01701

EXAMINER	
SISSON, BRADLEY L	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 10/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/996,658	**Applicant(s)** COULL ET AL.
	Examiner Bradley L. Sisson	**Art Unit** 1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 September 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on *20 September 2005*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-50*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: Interview Summary

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit: 1634

Continuation of 11. does NOT place the application in condition for allowance because: At pages 15-16 of the response received 20 September 2005, hereinafter the response, applicant's representative asserts that the objection to the specification should be withdrawn, citing that the citing of Advanced Display Systems Inc. is "misplaced." This traversal has not been found persuasive. As set forth In Ex parte Raible, 8 USPQ2d 1707, (BPAI, 1998)
"The examiner is of the opinion that the general incorporation by reference of the Bentley disclosure in appellant's specification is insufficient to support the specific disputed limitations of the present claims in the manner required by section 112 of the statute. We agree
* * *
We believe that the doctrine of incorporation by reference is of no avail to appellant in this regard since there is no specific indication in the instant specification of the particular features disclosed by Bentley which correspond to those intended for use in the here-claimed device; nor does the specification identify the specific portions of the patent which appellant may have intended to rely upon to supplement his disclosure. The purpose of incorporation by reference in an application of matter elsewhere written down is for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found. In re de Seversky , 474 F.2d 671, 177 USPQ 144 , (CCPA 1973). "

Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

While an applicant may utilize bibliographic citations in an application's specification so to establish the level of skill and/or state of the art at the time of filing, such documents, as is here, have not been properly incorporated so as to be useful in satisfying either the written description or best mode requirements of 35 USC 112, first paragraph. Additionally, to the extent that the documents contain essential subject matter required for the enablement of the claims, and said document is not an issued US patent, said documents cannot be relied upon for satisfaction of the enablement requirement of 35 USC 112, first paragraph. Appropriate action is required.

At page 17, bridging to page 19 of the response said representative directs attention to page 10 of the specification where the phrase "binding partner" is defined, and to pages 7-10 where "nuclei acid," "non-nucleic acid," "target sequences," "antibody," and "peptide nucleic acid" are defined and asserts that by said definitions, and the documents cited in the specification (page 19 of the response), the written description requirement has been met and that the rejection must be withdrawn.

The above argument has been fully considered and has not been found persuasive. It is noted with particularity that the claims have not been rejected under 35 USC second paragraph, as being indefinite. Rather, the claims have been rejected under 35 USC 12, first paragraph, as not being adequately described. The properties of the various elements recited, e.g., nucleic acid, non-nucleic acid, antibody, target sequence, etc., are shared by all members of that group of compounds. The specification has not provided an adequate written description of those members of the various groups such that one would be able to identify which a high degree of confidence, just which nucleic acid would best serve as a probe, or a target, or which antibody would best serve to bind an antigen of interest.

As presently worded, claim 1 requires the use of a "molecular probe" that when bound to a target organism, a binding partner immobilized on a solid support will also bind only those organisms where the molecular probe has been bound. In the case of a nucleic acid probe, which hybridizes to nucleic acid in the nucleus of a cell, the immobilized binding partner must somehow be able to reach all the way through the cell and into the nucleus, find the complex of nucleic acid probe - target nucleic acid, bind to it, all the while remaining immobilized to the external support. Clearly, even of this date, no such mechanism is known. A review of the specification is similarly silent as to how this most remarkable feat is to be accomplished.

As set forth at page 7 of the Office action, claim 12 specifically requires the use of "molecular probes [that stain] all organisms of a domain, kingdom, group, class, genus, species, taxon, subclass, subspecies, serotype or strain without regard to whether or not this represents the organism of interest and wherein the binding partner is specific for the domain, kingdom, group, class, genus, species, taxon, subclass, subspecies, serotype or strain that is the organism of interest." The specification does not provide an adequate written description of such compounds, much less an indication which compounds work best (or at all) with another. While said representative has directed attention to page 8 of the specification as listing numerous patents that teach PNAs, such disclosures, even if properly incorporated by reference, a point the Office does not concede, does not provide an adequate written description of those binding partners that are "specific for the domain, kingdom, group, class, genus, species, taxon, subclass, subspecies, serotype or strain that is the organism of interest."
At page 20, bridging to page 21 of the response, said representative attempts to distinguish University of California v. Eli Lilly and Co. (Fed. Cir. 1997) 41 USPQ2d at 1405. from the case at hand. At page 21 of the response said representative asserts that while UC disclosed rat cDNA, and not human cDNA, and was held to not provide an adequate written description of the claimed human cDNA, that the definitions of "molecular probe" and "binding partner" found in the body of the disclosure is somehow more descriptive of the particular compounds, and does satisfy the written description. This argument ahs been fully considered and has not been found persuasive towards the withdrawal of the rejection. Attention is also directed to the decision of Lilly wherein is stated:

"In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from

others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, is insufficient to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what it achieves as a result. "

Here, as in Lilly, the claims at issue comprise language that define the "molecular probe" and "binding partner "in terms of how they are to function, or the desired result to be achieved. The specification "does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus."

Acknowledgement is made of where at page 21, bridging to page 22 of the response, the decision of Capon v. Exhhar (Fed. Cir. August 2005), is identified. Argument is advanced that the facts of this case are more closely aligned to that of Capon, not to Lilly, and in like turn, the written description requirement should be withdrawn as "the claim limitations 'molecular probe' and 'binding partner' are embodied by compositions known in the art.". This argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection. Unlike Capon where expert testimony was presented, and which supported examples provided in the disclosure, the instant case presents no sworn declaration from an expert and a review of he disclosure finds but one example and then the example does not fully embrace the scope of claim 12, much less he scope of broader claims, e.g., claim 1. Therefore, with no convincing evidence having been presented, and no clear showing of how the situation at hand is non-analogous to that of Lilly, and finding no direction by said representative as to how and where the specification fully satisfies the written description requirement, the rejection of claims under 35 USC 112, first paragraph, is maintained.

At page 23, bridging to page 24 of the response said representative asserts that the enablement rejection must be withdrawn as the written description requirement has been met. This argument has not been found persuasive for as presented above, the specification is deemed to not provide an adequate written description of the claimed invention. Further, even if one of the reagents used in he claimed method were to be known in the art, a point the Office does not concede, the specification is essentially silent as to which combinations of reagents are useful and usable together. Such essential reaction conditions are not disclosed and the guidance provided as to general hybridization conditions does not fill the void created by the disclosrue, and which seemingly the public must in turn fill. Such non-disclosure of the full scope of conditions and reactants needed to practice the full scope of the claimed invention is an improper and unfair shifting of the burden of enablement to that of the public. It is applicant, not the public, which must fully enable the claimed invention. Therefore, and in the absence of convincing evidence to the contrary, the rejection of claims under 35 USC 112, first paragraph, as not being fully enabled by the disclosure is maintained.